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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/759,037	01/10/2001	David A. Mark	112701-138	3136

29157 7590 07/02/2003

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EXAMINER
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SHARAREH, SHAHNAM J

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 07/02/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/759,037

Applicant(s)

MARK ET AL.

Examiner

Shahnam Sharareh

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-- The MAILING DATE of this communication appears on the cover sheet with the corresponding address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 2/14/2003, 3/31/2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-3, 5-15 and 17-22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5-15, 17-22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submissions filed on March 31, 2003 and February 14, 2003 have been entered.

Claims 1-3, 5-15, 17-22 are pending in this application. Any rejection that is not addressed in this Office Action is considered withdrawn.

***Scope of the Pending Claims***

Examiner construes the scope of the pending claims to include compositions comprising any protein system so long as at least one of such protein systems consist of whey providing 15%-18% of the energy of the composition. Examiner base such interpretation on the use of the transitional phrase "comprising" which is employed in the preamble of the instant compositions and method claims. Accordingly, the instant enteral compositions comprise a protein source consisting of whey, a carbohydrate and a lipid source. The instant claims does not exclude the existence of other types of proteins in this composition. Neither does the body of the claim indicate that the whey protein source is the sole source of the protein energy in the instant compositions. Accordingly, instant compositions are capable of containing other types of proteins in combination with the instantly claimed amounts of whey protein.

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In addition, the instant limitation of free amino acid is inherent to the instant limitation "hydrolyzed whey protein," because naturally once a protein is hydrolyzed, it is broken down to its free amino acid base. Therefore, the limitation "free amino acid" is not viewed to further limit the claimed protein source beyond the limitation of "enzymatically hydrolyzed whey."

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-3, 5-15, 17-22 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-22 of copending Application No. 09/622,629. Applicant's intention to file a Terminal Disclaimer is noted when pending claims are allowed.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-3, 5-15, 17-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Henningfield et al US Patent 5,221,668 in view of Maubois et al US Patent 4,427,658 .

Henningfield discloses liquid nutritional products comprising a protein system which include partially hydrolyzed whey protein such as lactalbumin hydrolysate which provides about 18-24% of its calories (see col 19, lines 28-30). This protein source of Hennigfield consists of hydrolyzed lactalbumin which is a hydrolyzed whey protein, and

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It is well-established that merely selecting proportions and ranges is not patentable absent a showing of criticality. *In re Becket*, 33 USPQ. 33. *In re Russell*, 169 U.S.P.Q. 426. It has also been reasoned that where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Accordingly, absence of showing the criticality, it would have been obvious to one of ordinary skill in the art at the time of invention to optimize the amounts of such ingredients by routine experimentation, because as reasoned in *Becket*, *Russell* or *Aller*, such optimization is well within the level of the ordinary skill in the art.

Furthermore, absence of showing a criticality, it would have been obvious to one of ordinary skill in the art at the time of invention to prepare lactalbumins of Henningfield with those of Maubois, because, as taught by Henningfield, all lactalbumin hydrolysates are functional equivalents and the ordinary skill in the art would have had a reasonable expectation of success using any type of lactalbumin in preparing Henningfield's enteral compositions.

### ***Conclusion***

No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh whose telephone number is 703-306-5400. The examiner can normally be reached on 8:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, PhD can be reached on 703-308-1877. The

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further provides at least 18% of its energy source (col 9, lines 27-29; col 10, lines 31-43; col 10, lines 1-6). Henningfield's composition also contains lipids in amounts of 20-30% of the calories, and carbohydrates in amounts of 50-58% of the calories (see abstract table 1, col 6 lines 25-40, col 9 lines 31-40, claims 1, 4, 19 and 22). The lipid source of Henningfield is a mixture of medium chain triglyceride and corn oil or canola oil which are known long-chain triglycerides. (see col 12, lines 3-10).

Henningfield's composition also has a caloric density of about 1.2 to 1.5 Kcal/ml, and a calorie nitrogen ratio of about 112:1 to 145:1 which is above the instantly claimed amounts of at least about 90:1. The product of Henningfield et al also provide sufficient amount of vitamins in 1,500 Kcal (see col 13 lines 40-46, claims 21-22). Henningfield's composition can also contain beta carotene (see claims 22-26). Examiner acquiesces to the fact that Henningfield contains sodicum caseinate as an extras source of protein. However, the scope of the pending claims does not exclude such protein source. Henningfield teaches the use of zinc, vitamin C, selenium, taurine and I-carnetine (see table 2). Henningfield meets all limitations of the instant claims except the exact amounts of zinc, vitamin C, selenium, taurine and I-carnitine and a positive statement that its lactoalbumin hydrolysate is prepared enzymatically.

Maubois et al is used to show conventional methods of preparing enzymatic hydrolysate from whey proteins for incorporation into nutritional supplements for critically ill patients. Accordingly, the final product of Maubois contains whey hydrolysate and free amino acids. (see abstract, examples 1-3; col 18-20).

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fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1123.



Shahnam Sharareh, PharmD  
Patent Examiner, Art Unit 1617

ss

June 30, 2003